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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/214,982 01/14/99 HIRATA

Y 50026/014001

EXAMINER

HM22/0205

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BOSTON MA 02110

SANUD, C

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

02/05/01

Please find below and/or attached an Office communication concerning this application of proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/214,982

Applicant(s)
HIRATA et al.

Examiner
Christine J. Saoud

Group Art Unit
1647



☒ Responsive to communication(s) filed on Nov 30, 2000.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Claim 2 has been amended and claims 1 and 3-10 have been canceled as requested in the amendment of paper #13, filed 30 November 2000. Claim 2 is pending in the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed 30 November 2000 have been fully considered but they are not deemed to be persuasive.

Drawings

5. The drawings are objected to because Figure 4 should use capital letters to denote the two individual panels. Applicant requests that a substitute page be incorporated into the instant specification. This is not the correct procedure for affecting corrections to the Figures.
1. **Correction of Informalities** -- 37 CFR 1.85; 1097 O.G. 36
New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed,

the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Claim Rejections - 35 USC § 112

6. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record in paper #10.

The instant claim is directed to an isolated VEGF-D protein which is encoded by a nucleic acid which hybridizes under stringent conditions to the complement of the sequence of SEQ ID NO:2. The instant specification does not indicate that "isolated" refers to naturally occurring proteins, therefore, the claims encompass variants and mutants. The language of "highly stringent conditions" reasonably encompasses 10% variation in the nucleotide sequence, which would translate into as much as a 30% variation in the amino acid sequence of the encoded protein. However, the instant specification fails to provide a representative number of species which support the broad genus which is being claimed. The instant specification provides for the human

cDNA, and a mouse and rat cDNA which were isolated using the human cDNA for hybridization. The fact that the mouse and rat were isolated using the human cDNA as a template does not provide an enabling disclosure of the broad genus that is being claimed, which encompasses non-naturally occurring proteins which could have as much as 30% variation from the native proteins. The instant specification fails to provide sufficient guidance as to which portions of the protein should or could be modified and still retain one biological activity of the VEGF family. Further, the prior art fails to provide the guidance necessary to modify the claimed protein, because the prior art does not acknowledge the instant invention. It would be unpredictable to mutate and test in order to determine with modifications could be made and are encompassed by the instant claims. Applicant appears to have possession of and support for a claim to “an isolated, mammalian VEGF-D protein ...”, but not possession of and support for “an isolated VEGF-D protein” because this latter recitation still encompasses additions, substitutions, and deletions for which there is no written description, absent evidence to the contrary.

7. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites “hybridizing under highly stringent conditions”. Applicant asserts that support for this amendment can be found at page 4, paragraph 4. However, a review of the instant specification does not appear to provide a clear and definite definition of those conditions which are “highly stringent”. The specification contains many references to hybridization

conditions, none of which are labeled as "highly stringent". Additionally, at page 5 of the specification, it is indicated that "the hybridization condition can vary depending on the length of the probe, the labeling method, and the type of the target gene to be cloned". Therefore, the specification does not provide a clear, definite meaning for those hybridization conditions which are to be considered "highly stringent". Therefore, the claim is unclear and indefinite. This ground of rejection could be avoided by incorporation of those conditions which are to be encompassed by the claims, wherein the conditions find support in the instant specification as originally filed.

Conclusion

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 2, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud